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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,132	08/26/2003	Joerg Schiewe	1/1394	3249

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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT	PAPER NUMBER
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3771

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/648,132	Applicant(s) SCHIEWE ET AL.	
	Examiner Annette F. Dixon	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 31, 32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 15-30, 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 31, 32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>Feb. 23, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of **Claims 1-14 and 31-35** in the reply filed on July 26, 2006 is acknowledged. However, at the time the reply was filed, Applicant had not elected between the species represented in claims 33, 34, and 35. Therefore, a phone call was made to Mr. Alan Stempel, Applicant's representative, on September 19, 2006, requesting a complete election of the species represented in claims 33, 34, and 35. Applicant's representative elected claim 34 drawn to an inhalation device.
2. Claims 15-30, 33, and 35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 19, 2006.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
4. Specifically, the following documents are listed in the specification but have not been cited on an information disclosure statement nor submitted for this application:

WO 91/14468, WO 01/64268, EP 0918570, PCT/EP02/07038, WO 97/20590, EP 1100474, WO 94/07607, WO 99/16530, German Patent 10216101.1, EP 0860210, EP 1003478. Appropriate correction is required.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "2" and "2a" have both been used to designate the upper housing section (Page 29, Lines 13-24).
6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "29" has been used to designate both atomization facility, nozzle, and dispensing facility.
7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: alpha is not mentioned in the drawings.
8. The drawings are objected to because: (a) in numerous figures for example figure 1 and figure 2 the leader lines are not straight, (b) specifically in figure 2, the leader line for reference character "2" does not point to any element of the device, (c) the numbers used to denote the reference characters are handwritten and are confusing. Examiner requests Applicant provide formal drawings. Please see the draftsperson's review of the drawings. (d) in figure 4, Applicant is showing the movement of the device from an opened position to a closed position; however, Examiner finds Applicant's drawing confusing. Examiner suggest Applicant show the

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movement in different drawings, or provide dotted lines to denote the outline of the device at position B and provide a reciprocating arrow to denote the movement from start position, A, to final position, B.

9. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

10. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

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11. The disclosure is objected to because of the following informalities: On page 18-line 28, Applicant has used brackets within the disclosure. On page 19-line 24, "(container ball))" please correct to "(container ball)". Appropriate correction is required.
12. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

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- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward

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the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

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- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Objections

13. **Claim 10** is objected to because of the following informalities: Applicant's recitation of "housing middle section" and "housing lower section" appears to be a claimed element; however, these elements do not have antecedent basis in claim 10. Appropriate correction is required.

14. **Claim 11** is objected to because of the following informalities: Applicant recites "the release key"; however, this element does not have antecedent basis. Appropriate correction is required.

15. **Claim 12** is objected to because of the following informalities: Applicant recites "the locking member"; however, this element does not have antecedent basis. Appropriate correction is required.

16. **Claim 13** is objected to because of the following informalities: Applicant's recitation of "housing upper section" appears to be a claimed element; however, this element do not have antecedent basis. Appropriate correction is required.

17. **Claim 14** is objected to because of the following informalities: Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in the claims should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims. See MPEP § 608.01(m).

Claim Rejections - 35 USC § 112

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

19. **Claims 1-14** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20. Specifically in independent claim 1, Applicant recites "dissolved or suspended" as well as "liquid jet or aerosol of droplets". Both recitations allude to the element listed after the word "or" to be an equivalent of the word listed before. However, as Applicant has not asserted if these elements are in fact functional equivalents claims 1-14 are rejected for being indefinite.

21. Further, in dependent **claim 12**, Applicant recites "movement of the locking member and/or of the release key". The recitation of "and/or" renders the claim indefinite as Examiner is unsure whether the locking member moves, the release key moves, or both elements move.

22. **Claims 31, 32 and 34** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

23. Applicant's use of the word "at least" is unclear as the phrase "at least" implies another equivalent is acceptable. However, Applicant has not asserted what other

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possible equivalents are possible, therefore the independent claim 31 and its dependents are rejected for being indefinite.

24. Further, in independent **Claim 31** Applicant uses "and/or" which renders the claim indefinite. As well as "dissolved or suspended" and "liquid jet OR aerosol" Each of these terms render the claim indefinite and thus must be corrected.

25. **Claim 13** is rejected under 35 U.S.C. 112, sixth paragraph. Regarding claim 13, the word "means" is preceded by the word(s) "which prevent the housing upper section from being opened..." in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 102

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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27. **Claims 1-4, 9, 13, 14, 31, 32, and 34** are rejected under 35 U.S.C. 102(e) as being anticipated by Andersson (US 6,595,205).

28. **As to Claim 1**, Andersson discloses a device for the delivery of a predosed quantity of a drug in a dissolved or suspended form as a liquid jet or as an aerosol of droplets by delivery of the predosed quantity under pressure by dispensing facility, comprising an elastic element (134) for the storage of a predetermined quantity of energy, a mobile element (156) to which the predetermined quantity of energy can be fed and which can expose the dosed fluid quantity to a predetermined increase in pressure, characterized in that means for the respective introduction and removal of container cartridge (8) containing the drug into and from the accommodation chamber (the recess in which the container, 8, is inserted into the device and the valve stem is inserted into element 24) lying in the inside of the device and a means for the feeding of the pressurized drug to a dispensing facility firmly connected to the container cartridge (8) are provided (by the insertion of the nozzle into the element 24). Regarding the means for limitations, it should be noted that the device of Andersson has a pivot region (240) that not only supplies energy for the elastic element but also enables the device to be opened for the insertion of the canister (8) into the device. (Column 8 and 9).

29. **As to Claim 2**, Andersson discloses the container cartridge can be introduced into the accommodation chamber (the recess in which the container, 8, is inserted into the device and the valve stem is inserted into element 24) via an opening (the movement of element 6 via the pivot region 240) in the housing wall of the device.

30. **As to Claim 3**, Andersson discloses the container cartridge (8) can be introduced directly into its end-position in the device. (Column 8 and 9).

31. **As to Claim 4**, Andersson discloses the container cartridge (8), after its introduction into the housing opening (the movement of element 6 via the pivot region 240) can be transferred into its end-position by transport means in particular a transport carriage. When the container cartridge (8) is loaded the user must push element 2 past the first detent (222) this movement will inherently place the container (8) into a proper position for actuation to occur. Actuation occurs when the user has pushed element 2 past the second detent (244). (Column 8 and 9, Figures 5 and 6).

32. **As to Claim 9**, Andersson discloses the elastic element (134) for the storage of a predetermined quantity of energy is a helical spring (134) which is part of a locking claim means and via which a drive flange (supported by the movement of the spring to drive the piston downward) is connected to the pressure piston (156), is moved vertically. As discussed in claim 4, the actuation of the device occurs when element 2 is pushed past the second detent thereby compressing the spring (164) and pushing the canister deeper into the nozzle region (24).

33. **As to Claim 13**, Andersson discloses a closure arrest means (the interaction of the elements 222, 223, and 243), which prevents the housing upper section (2) from being opened as long as the compression spring (134) is not tensioned, and the pressure piston (156) thus projects into the housing upper section (2).

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34. **As to Claim 14**, as addressed in claim 13, Andersson discloses a closure arrest means comprising a bolt (243) which prevents the release of closure key (222) until the pressure piston (156) is in the position defined by the tensioned spring (124).

35. **As to Claim 31**, Andersson discloses a system for the delivery of a predosed quantity of a medico-therapeutically and/or medico-prophylactically effective substance in dissolved or suspended form as a liquid jet or an aerosol of droplets by delivery of the predosed quantity of the drug under pressure by a dispensing facility, comprising a device according to claim 1.

36. **As Claim 32**, Andersson discloses the accommodation chamber (the recess in which the container, 8, is inserted into the device and the valve stem is inserted into element 24) and the container cartridge (8) are developed to fit precisely.

37. **As to Claim 34**, Andersson disclose the device is for inhalation. (Abstract).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



AFD

September 29, 2006



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